

# Exhibit 8

*United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al.*  
*v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS

**Exhibit to the August 28, 2009 Declaration of Sarah L. Reid  
In Support of Defendants' Common Opposition to Plaintiffs'  
Motion for Partial Summary Judgment**



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Region IX  
Health Care Financing  
Administration

75 Hawthorne Street, 4th floor  
San Francisco, California 94105

Refer to: MCD-HCSG-SW

JUN 20 1997

AMP  
ISSUED -  
Best Price

Mr. Joe Kelly  
Director, Medi-Cal Policy Division  
California Department of Health Services  
714 P Street, Room 1786  
Sacramento, CA 95814

Dear Mr. Kelly:

This is in response to Jan Howard's inquiry to Mike Keough in HCFA's Medicaid Bureau regarding two drug policy issues in the State of California. After consultation with the Medicaid Bureau, we are providing guidance on the request for release of average manufacturer price (AMP) data and the status of the supplemental rebate agreements.

Regarding the first issue, we have determined that AMP and best price data will not be released by HCFA to states. Throughout the implementation of the Medicaid drug rebate program, HCFA has consistently rejected requests from states for the release of the pricing data submitted by manufacturers due primarily to confidentiality concerns. Rather, HCFA forwards a unit rebate amount for each drug to the states which is then used in the calculations of rebates.

In addition to the provisions in section 1927 of the Social Security Act prohibiting the disclosure by HCFA of the pricing information, major systems modifications would be required to accommodate the state's request. However, there is no prohibition on the state acquiring the information directly from the manufacturers; that is a matter between the state and the manufacturer. Further, we note that California has been operating a supplemental Medicaid rebate program for several years without HCFA supplying the pricing data.

Regarding the second issue, we have determined that the supplemental Medicaid rebate agreements between California and pharmaceutical manufacturers are approved. With this approval, the state agrees to report rebates received under the supplemental agreements to HCFA. Further, since these agreements are approved under the authority of section 1927 of the Social Security Act, all rebates, discounts, price reductions and any other arrangement related to prices and rebates under the agreements are excluded from the calculations of average manufacturer prices and best price for purposes of the Medicaid drug rebate program.

If you or your staff have any questions, please contact Stephanie Wall, Health Insurance Specialist, at (415) 744-3565.

Sincerely,

Richard Chambers  
Associate Regional Administrator  
Division of Medicaid

cc: Jan Howard, Chief, Medi-Cal Contracting Section  
Mike Keough, HCFA/Medicaid Bureau

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